Premarket notification [510(K)] Summary

As per 21 CFR. Section 807.92(C)

APR 13 2007

Applicant	SarMed srl Località Sa Stoia 09016 Iglesias Italy
Contact	Dr. Claudio Rossi QA/RA Manager Ph : 0039 0535 51159 Fax : 0039 0535 52605 quality@medica.it
Trade Name	Single Use Esophageal Manometry Catheters and Single Use Ano-Rectal Manometry Catheters
Common name	Esophageal and Ano-Rectal Manometry Catheters
Classification name	Gastrointestinal motility monitoring system 21 CFR Sec. 876.1725
Product Code	KLA
Predicate Devices	Medtronic Single Use Esophageal Manometric Catheter And Medtronic Single Use Ano-Rectal Manometric Catheter **(K032138)** Mediplus Single Use Ano-Rectal Manometry Catheter **(K031617)** Mediplus Esophageal Manometry Catheter **(K013704)**

DEVICE DESCRIPTION

The SarMed Single Use Esophageal Manometry and Ano-Rectal Manometry Catheters are available in some different configurations, respect to number of lumen and number of tubes. They are designed to be connected to a manometric infusion pump and allow, by the way of a defined number of holes, the measurement of pressure on the Gastro-Intestinal and Ano-Rectal Tract.

INTENDED USE

The SarMed Single Use Esophageal Manometry Catheters and Ano-Rectal Manometry Catheters are intended for Manometry analysis of Gastro-Intestinal and Ano-Rectal Tract.

INDICATIONS FOR USE

The SarMed Single Use Esophageal Manometry Catheters and Ano-Rectal Manometry Catheters are indicated for patients where Gastro-Intestinal and Ano-Rectal tracts pressure measurements are required, such as for detection of GI tract disorders. The products are to be used by a trained physician.

TECHNOLOGICAL CHARACTERISTICS

The catheters in object are technologically equivalent to the predicate devices above listed, both in physical than in design characteristics. Like all the Predicate Devices listed, the SarMed Ano-Rectal and Esophageal Manometry Catheters are made with Medical Grade plastics that has been used in a wide range of Medical applications :

Tab 5-1 MATERIAL OF BODY CONTACT PARTS

	ESOPHAGEAL	ANO-RECTAL
CANNULA	PVC	PVC
TUBES	PVC	PVC
BALLOON	NA	LATEX OR LATEX FREE RUBBER

TESTING AND SAFETY

The SarMed Single Use Esophageal Manometry Catheters and Ano-Rectal Manometry Catheters has been tested for biocompatibility and meets the requirements of **ISO 10993-1** schemes, for the intended use of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Dr. Antonio Rossetti
QA/RA Manager
SarMed s.r.l.
Via Degli Artigiani, 6
41036 Medolla
ITALY

APR 13 2007

Re: K062362
Trade/Device Name: Single Use Esophageal Manometry Catheters and Single Use Ano-Rectal Manometry Catheters
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: KLA
Dated: March 27, 2007
Received: March 30, 2007

Dear Dr. Rossetti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) : K062362

Device Name : Single Use Esophageal Manometry Catheters and Single Use Ano-Rectal Manometry Catheters

Indications for Use :

The SarMed Single Use Esophageal Manometry Catheters and Ano-Rectal Manometry Catheters are indicated for patients where Gastro-Intestinal and Ano-Rectal tracts pressure measurements are required, such as for detection of GI tract disorders. The products are to be used by a trained physician.

Prescription Use (Part 21 CFR 801 Subpart D)	**YES**	~~AND~~/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	**NO**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepton

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062362